

April 24, 2002

OFFICE OF RESEARCH AND DEVELOPMENT LETTER

**REQUEST FOR PROPOSALS (RFP) FOR SUPPORT TO ENHANCE
RESEARCH AND DEVELOPMENT PROGRAM
HUMAN AND ANIMAL PROTECTION PROGRAM ACTIVITIES**

1. Announcement. The Veterans Health Administration (VHA) Office of Research and Development (ORD) announces a program to enhance the ability of Department of Veterans Affairs (VA) facilities to meet accreditation and regulatory requirements for the conduct of research. All VA medical centers, healthcare systems, or consortia of VA facilities with active research programs are invited to compete for one time, non-renewable funding of up to \$50,000. Letters of Intent (LOI) may be submitted by May 10, 2002, and full proposals by June 14, 2002, in accordance with the following guidelines.

2. Background. The expertise and resources required to oversee and conduct a research program involving humans or animals as research subjects have increased exponentially over the past decade. This increase is due to the expansion of the ethical principles for the conduct of research as well as the accompanying development of Federal regulations governing the conduct of research. Because of these increased demands, research and development (R&D) staff at VA medical centers and universities has found it difficult to maintain their expertise and obtain the required resources to effectively manage their programs. Resource deficiencies have resulted in some VA and University-based programs being suspended and/or reprimanded. Some programs have voluntarily closed. This initiative is designed to provide some of the resources necessary to attain the highest possible standards for the ethical conduct of research.

3. Scope of Support. VA facilities may request funds to support and enhance human and animal protection program activities (HAPPA). These activities may focus on the R&D Committee, the Institutional Review Board (IRB) and/or Human Research Protection Program (HRPP), and/or the Institutional Animal Care and Use Committee (IACUC). The activities that may be supported by this funding include, but are not limited to the following:

- a. Development of infrastructure and/or technology.
- b. Purchase of equipment, including computers and/or software, to enhance both the research program's compliance with regulations and accreditation standards and its ability to protect human and/or animal research subjects.
- c. Creation of systems to track research protocols, investigator and/or committee training, and/or compliance with policies, regulations, and/or accreditation standards.

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d. Creation of tools to link processes such as tracking of adverse events, Data Safety and Monitoring Board (DSMB) reports, MedWatch reports, or other sources of information that may impact on protocol review.

e. Development of systems to coordinate administrative activities and approval of protocols by all applicable committees and/or subcommittees.

f. Creation of systems or processes to monitor active research protocols including those monitoring activities required by IRBs, the VA and other Federal agencies or creation of a mechanism to integrate these monitoring activities into the facility's Quality Assurance and/or Quality Improvement Programs.

g. Purchase of reference materials, training programs, or other educational endeavors to meet educational requirements related to the research program.

4. Eligibility. All VA facilities with currently active R&D programs are eligible to apply. VA medical centers that have a joint program with one or more other VA medical centers may submit joint applications. VA medical centers utilizing a university affiliate's IRB and/or IACUC may request support only for VA activities (e.g., communication, coordination, tracking and monitoring, or R&D committee), but not for the IRB and/or IACUC at the affiliate.

5. Budget. Up to \$5 million will be committed for this program. Each VA medical center applying for funding may request up to \$50,000. The number of proposals to be funded and the amount of funding for each proposal is dependent on the merit of the proposals received and the size and complexity of the research program(s).

6. LOI. To be eligible, an LOI must be submitted to ORD prior to submitting a full proposal. Proposals will only be accepted from a medical center that has received favorable review of a LOI.

a. The LOI needs to contain the following information:

(1) Name of the VA medical center(s)

(2) Name and contact information of the person completing the LOI

(3) The location of the IRB and IACUC (VA medical center, other VA medical center, university).

(4) A short summary (limited to one page) of the proposal topic or idea.

(5) Name, title, and signature of the Associate Chief of Staff for R&D at each facility.

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b. To ensure receipt by close of business May 10, 2002, the LOI sent by mail needs to be forwarded (preferably by overnight carrier) to:

Department of Veterans Affairs
Office of Research and Development (12)
Attn: RFA – R&D HAPPA
810 Vermont Ave., N.W.
Washington, DC 20420

Phone: 202-565-8440

c. LOIs may be faxed to: 202-565-8738.

NOTE: *VA medical centers that submit an LOI will be notified of acceptance in sufficient time to submit a full proposal by the June 14, 2002, deadline.*

7. Review of Proposals. Proposals will be reviewed in August 2002 and funding decisions made prior to September 1, 2002.

8. Evaluation Criteria. The evaluation criteria for proposals will include, but not be limited to:

a. The relationship of proposed activities or equipment/infrastructure to the current research program.

b. Justification for any new equipment or software.

c. The ability of the institution to sustain the proposed activities after the funding period has ended.

9. Application Instructions. If applying, the application needs to be prepared in accordance with instructions in Attachment A.

10. Timeline

a. Deadline for LOI in VA Central Office-----May 10, 2002

b. Proposal Due in VA Central Office-----June 14, 2002

c. Review of Proposals-----August 2002

d. Funding of projects -----September 1, 2002

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11. Inquiries. Inquires may be addressed to Dr. Brenda A. Cuccherini at 202-408-3614, or by electronic mail at brenda.cuccherini@hq.med.va.gov.

John R. Feussner, M.D., M.P.H.
Chief Research and Development Officer

Attachment

DISTRIBUTION: CO: E-mailed 4/24/2002
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ATTACHMENT A

**INSTRUCTIONS FOR SUBMISSION OF PROPOSALS
SUPPORT TO ENHANCE RESEARCH AND DEVELOPMENT PROGRAM
HUMAN AND ANIMAL PROTECTION PROGRAM ACTIVITIES**

1. One proposal will be accepted from each Department of Veterans Affairs (VA) medical center, healthcare system, or consortium of VA facilities that have currently active research programs and have received favorable review of a Letter of Intent (LOI). To qualify for funding, the research program should be in need of additional support to ensure compliance with accreditation and regulatory standards.

2. **Format.** Proposals must be unbound and consist of single-spaced typed pages with letter-quality print. All text must be prepared with at least 11-point font, with no more than fifteen characters per inch and no more than six lines per inch. Proposals that exceed specified page limitations will be administratively removed from the review process and not reviewed.

3. **Cover Sheet.** A cover sheet (one page only) listing the following information in the order specified:

a. Request for Support to Enhance Research and Development Program Human and Animal Protection Program Activities (HAPPA).

b. Name and location of the primary VA facility responsible for the administration of the program, if funded. If the proposal is from an integrated healthcare system or consortium, provide the name and location of the individual medical centers in the system or consortium.

c. Administrative contact name, telephone, and fax number.

d. **Total funding requested.** If the proposal is from an integrated healthcare system or consortium, specify the amount requested for each of the individual medical centers in the system or consortium.

e. Name, title, and signature of the Associate Chief of Staff (ACOS) for Research and Development (R&D) at each facility.

f. Name, title, and signature of the medical center Director at each facility.

g. An itemized list of equipment and software requested, if any. If the proposal is from an integrated healthcare system or consortium, indicate which items will be used at each individual medical center. Specify the proposed location of each equipment item requested.

4. **Review and Approval.** Attach documentation of review and approval by the R&D Committee(s).

5. **Budget.** Include an itemized budget with a justification for any equipment or software requested

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6. Narrative. The narrative is limited to five pages and is to include:

a. A brief description of the current research program(s), including:

(1) The number of active research protocols at each facility. Include a breakdown of active protocols using human subjects and animal subjects. Include all active protocols regardless of funding status or source.

(2) The number of protocols reviewed annually by the R&D Committee and the number of actions taken by each IRB, including:

(a) The number of initial, continuing and expedited reviews;

(b) The number of protocols determined to be exempt; and

(c) Any other actions taken such as review of serious adverse events or expedited review of minimal changes to a protocol.

(3) A description of the relationship between the Institutional Review Board IRB(s) and the R&D committee(s), including communication, review functions, etc.

(4) A brief description of the current components of the human subjects protection program(s), including all committees, staff, equipment, and processes such as tracking of protocols, training of staff, etc.

b. A description of the proposed activities, work, or equipment for which support is requested. Identify the impact of these activities on the current research program(s) and how the activities will be integrated into the current program(s).

c. A description of the facilities' current resources.

7. Submission of Proposals: Submit the original and ten copies by Federal Express or other overnight door-to-door delivery service to:

Department of Veterans Affairs
Office of Research and Development (12)
Attn: RFA – R&D HAPPA
810 Vermont Ave., N.W.
Washington, DC 20420

Phone: 202-565-8440

8. Deadline. Proposals must be received in the Office of Research and Development (ORD) by close of business June 14, 2002.